

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ALLERGAN USA, INC., ALLERGAN
HOLDINGS UNLIMITED COMPANY, and
EDEN BIODESIGN, LLC,

Plaintiffs,

v.

SUN PHARMACEUTICAL INDUSTRIES
LIMITED,

Defendant.

C.A. No. 19-1727-RGA

MEMORANDUM OPINION

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ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me is Plaintiffs' motion to dismiss a counterclaim pursuant to Rule 12(b)(6) and to strike four affirmative defenses pursuant to Rule 12(f). (D.I. 354). The motion has been fully briefed. (D.I. 355, 358, 363). For the reasons set forth below, Plaintiffs' motion is granted in part and denied in part.

I. BACKGROUND

On September 13, 2019, Plaintiffs Allergan USA, Inc., Allergan Holdings Unlimited Company, and Eden Biodesign, LLC (collectively, "Allergan" or "Plaintiffs") filed their Complaint alleging infringement of U.S. Patent Nos. 9,675,587 (the "'587 Patent") and 10,188,632 (the "'632 Patent") against Defendant Sun Pharmaceutical Industries Limited. The alleged infringement is based on Sun filing Abbreviated New Drug Application ("ANDA") No. 213447 with the FDA. Over the course of the litigation in this case, Allergan filed continuation applications and prosecuted patents belonging to the patent family at issue. Allergan later obtained U.S. Patent Nos. 11,007,179 (the "'179 Patent"), 11,090,291 (the "'291 Patent"), and 11,160,792 (the "'792 Patent"), and asserted them against Sun in July 2021, August 2021, and November 2021, respectively. The actions asserting these patents were consolidated with this action.

Allergan obtained U.S. Patent Nos. 11,229,627 (the "'627 Patent") and 11,311,516 (the "'516 Patent") in January 2022 and April 2022, respectively. Allergan filed an Amended Complaint asserting the '627 Patent and the '516 Patent against Sun. (D.I. 343). Sun filed its Answer on May 16, 2022. (D.I. 346). Sun later filed an Amended Answer on May 27, 2022. (D.I. 349). In its Amended Answer, Sun raises, among other things, a counterclaim and affirmative defense that the '516 Patent is unenforceable because of Allergan's unclean hands. (*Id.* at 8-10, 15-18).

Sun also pleads three other affirmative defenses. Sun alleges that the '627 Patent's and '516 Patent's claims are barred by prosecution history estoppel and/or judicial estoppel, that Allergan's claims are barred by the equitable doctrines of waiver, estoppel, and/or laches, and that Allergan's claims are barred by the doctrine of patent misuse. (*Id.* at 10).

On June 10, 2022, Allergan filed the pending motion to dismiss the counterclaim of unclean hands under Rule 12(b)(6) for failure to state a claim upon which relief can be granted and to strike the related affirmative defenses under Rule 12(f).

II. LEGAL STANDARD

A. MOTION TO DISMISS COUNTERCLAIM UNDER RULE 12(b)(6)

Federal Rule of Civil Procedure 8 requires a complainant to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). Rule 12(b)(6) allows the accused party to bring a motion to dismiss a claim for "failure to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). A Rule 12(b)(6) motion may be granted only if, accepting the well-pleaded allegations in the counterclaim complaint as true and viewing them in the light most favorable to the complainant, a court concludes that those allegations "could not raise a claim of entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007).

The factual allegations do not have to be detailed, but they must provide more than labels, conclusions, or a "formulaic recitation" of the claim elements. *Id.* at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)."). Moreover, there must be sufficient factual matter to state a facially plausible claim to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The facial plausibility standard is satisfied when the complaint's factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* ("Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops

short of the line between possibility and plausibility of entitlement to relief.” (internal quotation marks omitted)).

B. MOTION TO STRIKE UNDER RULE 12(f).

“[P]ursuant to Rule 12(f), the Court may strike from a pleading any insufficient defense.”

Wyeth Holdings Corp. v. Sandoz, Inc., 2012 WL 600715, at *4 (D. Del Feb. 3, 2012) (internal quotation marks omitted). “When ruling on a motion to strike, ‘the [c]ourt must construe all facts in favor of the nonmoving party and deny the motion if the defense is sufficient under law.’” *Sun Microsystems, Inc. v. Versata Enters., Inc.*, 630 F. Supp. 2d 395, 402 (D. Del. 2009) (quoting *Proctor & Gamble Co. v. Nabisco Brands, Inc.*, 697 F. Supp. 1360, 1362 (D. Del. 1988)). “However, a court is not required to accept affirmative defenses that are mere ‘bare bones conclusory allegations,’ and may strike such inadequately pleaded defenses.” *Sun Microsystems*, 630 F. Supp. 2d at 408 (quoting *Cintron Beverage Group, LLC v. DePersia*, 2008 WL 1776430, at *2 (E.D. Pa. Apr. 15, 2008)). “A motion to strike a defense should not be granted ‘unless the insufficiency of the defense is clearly apparent.’” *Sun Microsystems*, 630 F. Supp. 2d at 402 (quoting *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181, 188 (3d Cir. 1986), *rev’d on other grounds*, 505 U.S. 504 (1992)).

III. DISCUSSION

Sun claims that Allergan misused Sun’s confidential information to prosecute the ’516 Patent and then asserted that patent against Sun. Sun alleges that prior to the date suit was filed in 2019, Allergan consistently prosecuted patent applications that recited “colloidal silica” or “colloidal silicon dioxide” as a required limitation in “each and every claim.” (D.I. 349 at 8-9, 16-17). Sun alleges that after Allergan “had accessed Sun’s confidential information regarding its ANDA Product formulation,” Allergan eliminated the limitation requiring “colloidal silicon dioxide” from claims in the patent application that led to the ’179 Patent. (*Id.* at 9, 17). Sun alleges

that Allergan later used Sun's confidential information to draft claims in the '516 Patent to "not explicitly require colloidal silica in an improper attempt to cover Sun's ANDA Product Formulation, which [Allergan] did not invent." (*Id.* at 17). Sun alleges that Dr. Tim Costello, one of the inventors named on the '516 Patent, has stated "that he never invented any eluxadoline composition that did not include colloidal silica." (*Id.*).

In its Answering Brief (D.I. 358), Sun disavows the theory put forth in its Amended Answer. Sun still asserts a claim of unclean hands, but Sun does not allege that Allergan misused confidential information it obtained from Sun during litigation. "Sun is not alleging a violation of the Stipulated Protective Order or any *fraudulent* use of Sun's confidential information." (*Id.* at 16). Sun, instead, argues, "Allergan gleaned Sun's confidential noninfringement position from the 2020 *Markman* proceedings and then ran to the Patent Office to seek new claims to formulations it did not invent." (*Id.*). Allergan replies that Sun's briefing should be grounds for granting Allergan's motion as it refutes the facts Sun alleges in its Amended Answer. (D.I. 363 at 9). I decline to read the facts or new theories from Sun's brief into Sun's Amended Answer. "As the Third Circuit has stated, '[i]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.'" *M2M Sols. LLC v. Telit Commc'ns PLC*, 2015 WL 4640400, at *3 (D. Del. Aug. 5, 2015) (quoting *Com. of Pa. ex rel. Zimmerman v. PepsiCo. Inc.*, 836 F.2d 173, 181 (3d Cir. 1988)). This new theory and the facts supporting it are "not entitled to consideration in the pleading stage." *Id.* Therefore, Sun's new theory does not factor in my determination that Sun has stated a claim that the '516 Patent is unenforceable under the doctrine of unclean hands.¹

¹ Sun will have the burden of proving the facts it has asserted in its Amended Answer. I do not opine on whether Sun's theory discussed in its Answering Brief states a claim for unclean hands. I also am not sure why Sun would pursue the theory stated in its Answering Brief, since the

A. UNCLEAN HANDS COUNTERCLAIM

1. Pleading Standard

Allergan asserts that Sun's counterclaim for unclean hands sounds in fraud. (D.I. 355 at 6; D.I. 363 at 2-5). Allergan argues Sun's unclean hands counterclaim must be pled with particularity as required by the Federal Rule of Civil Procedure 9(b) standard.

Sun contends that its unclean hands counterclaim is based on unconscionability and bad faith. Sun argues it only needs to meet Federal Rule of Civil Procedure Rule 8's less demanding requirements for pleading its counterclaim because it does not sound in fraud. (D.I. 358 at 16). In its Amended Answer, Sun alleges, "Plaintiffs misused Sun's confidential information relating to its eluxadoline ANDA product formulation to obtain claims that Plaintiffs did not invent and then asserted those claims against Sun." (D.I. 349 at 8, 16). Sun characterizes these allegations as a type of "litigation misconduct." (*Id.* at 9, 17).

"Unclean hands is an equitable defense requiring the showing of five elements: (1) the party seeking affirmative relief (2) is guilty of conduct involving fraud, deceit, unconscionability, or bad faith (3) directly related to matter in issue (4) that injures other party (5) and affects balance of equities between litigants." *Sonos, Inc., v. D&M Holdings Inc.*, 2016 WL 4249493, at *5 (D. Del. Aug. 10, 2016) (quoting *Sun Microsystems*, 630 F. Supp. 2d at 410). The conduct "must have an immediate and necessary relationship to the equity which [the plaintiff] seeks to obtain in the matter in litigation." *Sun Microsystems*, 630 F. Supp. 2d at 410 (quoting *Blanchette v. Providence & Worcester Co.*, 428 F. Supp. 347, 357 (D. Del. 1977)).

premise is that the claims lack written description. If they do, I will not need to reach the equitable defenses. If they do not, the equitable defenses will fail. Thus, it seems the theory adds nothing.

The pleadings standard for unclean hands depends on the specific conduct alleged. A counterclaim or affirmative defense that alleges fraudulent conduct must be pled with particularity under Rule 9(b). *See, e.g., Sonos*, 2016 WL 4249493 at *5. Allegations that are founded on other theories, however, need only meet the Rule 8 standard. “*Sonos* is authority for the proposition that an unclean hands defense based on fraud or misrepresentation must satisfy the pleading requirements of Rule 9(b), but not for the broader proposition that every invocation of unclean hands must satisfy Rule 9(b).” *AbbVie Inc. v. Boehringer Ingelheim Int'l GmbH*, 2018 WL 2604825, at *1 (D. Del. June 4, 2018).

I find that Rule 8 is the correct standard to apply in the present case. Sun has only claimed that Allergan has committed litigation misconduct, not fraud. In its Amended Answer, Sun alleges that Allergan misused Sun’s confidential information, which Allergan obtained from Sun through the course of this litigation.² Specifically, Sun alleges that Allergan used Sun’s confidential information to draft the claims of the ’179 Patent and the ’516 Patent in an improper attempt to cover Sun’s ANDA formulation.³ Courts have applied Rule 8 to analyze similar unclean hands

² Allergan also contends, “Sun is necessarily claiming that Allergan’s [patent] prosecutors pursued claims by either intentionally withholding [] testimony or knowingly misrepresenting to the PTO that Allergan invented [certain] claims.” (D.I. 363 at 4). Allergan argues that the conduct Sun accuses Allergan of is akin to “defrauding the PTO,” which must be pled in accordance with Rule 9(b). (*Id.*). Sun’s amended answer, however, does not allege nor claim that Allergan committed inequitable conduct. Therefore, I find Rule 9(b) is not applicable to analyzing the sufficiency of Sun’s counterclaim of unclean hands.

³ Allergan cites to *Kingsdowne Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988), for the proposition “that there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor’s product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor’s product the applicant’s attorney has learned about during the prosecution of a patent application.” Sun claims that Allergan drafted its claims to cover an invention that Allergan had not invented, using Sun’s confidential information, so that it would cover Sun’s ANDA formulation. The conduct goes beyond simply drafting claims to cover a known competitor’s product. *See also Natera, Inc. v. Genosity, Inc.*, 2022 WL 767602 (D. Del. March 14, 2022).

pleadings. *See, e.g., Jazz Pharms., Inc. v. Roxane Lab'ys, Inc.*, 2013 WL 6858765, at *5 (D.N.J. Dec. 30, 2013) (applying Rule 8 to analyze the defendant's unclean hands defense alleging plaintiff used confidential information obtained in the course of litigation to prosecute continuation patent).

Therefore, I find that Rule 8 should apply to determine whether Sun has sufficiently pled its counterclaim for unclean hands.

2. Sufficiency of the Pleading

Allergan asserts that Sun's allegations fail to meet Rule 8's requirements. (D.I. 363 at 7). Allergan argues Sun's counterclaim should be dismissed because Sun's Opposition Brief "conced[es] that none of Sun's confidential information was actually misused" by Allergan, and thus is grounds for dismissal. (D.I. 363 at 3, 9).

Sun argues that it has sufficiently stated a claim for unclean hands. In its Amended Answer, Sun alleges that Allergan misused Sun's confidential information, which Allergan obtained from Sun, to prosecute the '516 Patent in a manner to cover Sun's ANDA formulation, and then assert that patent against Sun. (D.I. 349 at 9-10, 17-18). Sun argues such conduct is unconscionable and should render the '516 Patent unenforceable against Sun. (D.I. 388 at 15).

I find that Sun's Amended Answer states a plausible claim for unclean hands. Sun has alleged facts to show that Allergan changed its strategy for prosecuting patents – by eliminating the inclusion of "colloidal silica" or "colloidal silicon dioxide" as a limitation to certain claims – after it had access to Sun's confidential information pertaining to Sun's ANDA formulation. The present case is similar to *Natera, Inc. v. Genosity, Inc.*, 2022 WL 767602 (D. Del. March 14, 2022). In *Natera*, the court found that Genosity had sufficiently pled an affirmative defense of unclean hands by alleging: (1) Natera never claimed ArcherDX's method in previous prosecution at the PTO, (2) one of Natera's executives left Natera to work at ArcherDX, (3) that executive gained

access to the confidential information relating to ArcherDX's technology, (4) that executive then returned to Natera, and (5) Natera then drafted the claims of its patent in an attempt to cover ArcherDX. *Id.* at *5. Sun alleges a similar timeline of changing patent prosecution strategy after gaining access to confidential information.⁴ Therefore, I find Sun has alleged facts to state a plausible claim that Allergan acted with unclean hands, and that the '516 Patent is therefore unenforceable.⁵

B. SUN'S AFFIRMATIVE DEFENSES

1. Unclean Hands

Allergan argues Sun's affirmative defense of unclean hands should be struck under Rule 12(f) because Sun failed to plausibly plead its corresponding counterclaim. (D.I. 355 at 9).

I find that Sun's affirmative defense of unclean hands is properly pled. The pleading standard for an affirmative defense is less demanding than that of a claim or counterclaim. *See Internet Media Corp. v. Hearst Newspapers, LLC*, 2012 WL 3867165, at *3 (D. Del. Sept. 6, 2012) (noting that affirmative defenses "need not be plausible to survive" under Rule 8(c)). Sun states a plausible claim that the '516 Patent is unenforceable due to the doctrine of unclean hands.

⁴ Even though in *Natera* unclean hands was pled as an affirmative defense, which just needed to comply with Rule 8(c), and not Rule 8(a)'s *Twombly* and *Iqbal* standard, *Senju Pharm. Co., v. Apotex, Inc.*, 921 F. Supp. 2d 297, 303 (D. Del. 2013), *Natera* is still informative. The court there noted that "a plausible inference can be drawn from these alleged facts that Natera misused [the] confidential information to obtain claims that it did not invent and then asserted these claims against Genosity." *Natera*, 2022 WL 767602, at *5.

⁵ Sun's Amended Answer states Sun "reserve[s] the right to rely upon the doctrine of unclean hands to bar the enforceability of U.S. Patent Nos. 11,007,179, 11,090,291, 11,160,792, and 11,229,627." (D.I. 349 at 16 n.2). In its Amended Answer, however, Sun has pled that just the '516 Patent is unenforceable due to Allergan's unclean hands. Therefore, my determination that Sun has stated a claim that Allergan has unclean hands only extends to the '516 Patent. "Reserving a right" does not plead a counterclaim or an affirmative defense.

Therefore, because Sun alleges the same facts for its affirmative defense, Sun's defense meets the Rule 8(c) standard.

2. Prosecution History Estoppel and/or Judicial Estoppel

Allergan argues that Sun's Fifth Defense of prosecution history estoppel and/or judicial estoppel should be "stricken to the extent that it 're-allege[s] and incorporate[s] by reference' [Sun's] unclean hands defense." (D.I. 355 at 10 n.3).

Allergan only seeks to strike this affirmative defense to the extent it re-alleges facts from the unclean hands defense. Because I will not strike the unclean hands affirmative defense, I will not strike the Fifth Defense, either.

3. Waiver, Estoppel, and Laches

In its Answering brief, Sun agrees to withdraw its Sixth Defense of waiver, estoppel, and laches. (D.I. 358 at 1 n.1). Therefore, I will strike it.

4. Patent Misuse

Allergan argues that Sun's Seventh Defense of patent misuse should be struck if the unclean hands defense is struck because they rest on the same allegations. (D.I. 355 9-10).

Since the premise of Allergan's request is not met, I will not strike the Seventh Defense.

IV. CONCLUSION

For the reasons stated above, Plaintiffs' motion is GRANTED in part and DENIED in part. An appropriate order will issue.